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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Schade, Deborah A., et al.) Group Art Unit: 1617
Serial No.: 09/381,484)
Filed: February 28, 2000) Examiner: Shengjun Wang
For: Use of Docosahexaenoic Acid)
and Arachidonic Acid Enhancing)
The Growth of Preterm Infants) Deposit Account: 50-2548

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPLICANT'S REPLY BRIEF TO EXAMINER'S ANSWER

Dear Sir:

Applicant submits the present Reply Brief in accordance with 37 C.F.R. § 41.41. The Examiner's Answer has a mailing date of July 13, 2006, making the present Reply Brief due on or before September 13, 2006. This Reply Brief is being deposited as First Class Mail on the date noted on the attached Certificate of Mailing and is believed to be timely filed. The present Reply Brief is intended to be responsive to each and every new issue raised in the Examiner's Answer. Please charge any additional fees that may be required to Deposit Account No. 50-2548.

Arguments

In the Examiner's Answer, the Examiner repeats his previous grounds and arguments for rejection and, in response to the Applicant's arguments, asserts that "the recitation 'for enhancing the weight gain' has not been given patentable weight because the recitation occurs in the preamble." (Examiner's Answer, Page 6). This argument was originally presented in an Office Action mailed May 7, 2002. Applicant provided arguments regarding this argument on September 9, 2002 in its response to that Office Action. The argument was not repeated in the next substantive Office Action, mailed May 14, 2003, or any Office Action thereafter. Because Applicant believed that this argument had been previously overcome, the argument was not addressed in Applicant's Appeal Brief. The argument is addressed herein, below.

In his Answer, the Examiner first argues that the recognized benefit of weight gain is an advantage which would flow naturally from the suggestion of the prior art and, therefore, a *prima facie* case of obviousness was established. However, the Examiner does not dispute that the only case cited in his Answer, *Ex Parte Obiaya*, deals with product or composition claims. While it is true that the discovery of a new property or use of a previously known composition does not impart patentability to the composition, the same is not true for method claims such as those presented here.

As Applicant explained in more detail in its Appeal Brief, a newly discovered use of something that was already known is patentable as a method of use. The present invention claims a new use of a composition for a specific

purpose (i.e. enhancing the weight gain of preterm infants), not the composition itself. As such, an inherency argument should not apply.

The Examiner's failure to recognize this distinction is demonstrated by his statement: "Therefore, to make such infant formula as claimed herein and use the same for feeding preterm infant would have been obvious to one of ordinary skill in the art." The claimed method is not merely "for feeding to preterm infants," as stated by the Examiner. Rather, it is for feeding to preterm infants to respond to a particular need and obtain a particular claimed result – enhancement of weight gain. This is not an inherent property in the context of a composition or product claim, but is instead a direct method limitation that has been heretofore unknown.

Even if this Board finds that inherency arguments can be maintained in reference to new process or method claims, an inherency argument should not be maintained in connection with an obviousness rejection. "The inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on that which is unknown." *In re Shetty*, 566 F.2d 81, 195 USPQ 753 (CCPA 1977) (citing *In re Adams*, 356 F.2d 998, 148 USPQ 742 (CCPA 1966)); see also MPEP § 2141.02(V); *In re Spormann*, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966); *In re Rijckaert*, 9 F.2d 1531, 28 USPQ2d 1955 (Fed. Cir. 1993). In the present case, the ability of DHA and ARA to increase the weight gain in preterm infants was an unknown advantage. If the advantage was unknown among those skilled in the art, it follows that it cannot also be obvious.

In addition, the Examiner's renewed argument that the "weight gain" limitation is only in the preamble is simply wrong. The limitation for enhancing weight gain does not merely occur in the preamble of the claim, but also occurs throughout the body of the claim. Applicant's only pending independent claim, Claim 1, recites:

1. A method for enhancing the weight gain of preterm infants comprising administering to said infants a weight gain enhancing amount of DHA and ARA, wherein the weight gain enhancing amount comprises DHA in an amount of at least about 10 mg/100 kcal and ARA in an amount of at least about 30 mg/100 kcal, wherein the DHA and ARA are added into nutritional products or nutritional supplements for preterm infants.

Accordingly, regardless of whether the Examiner gives the preamble patentable weight, the recitation of enhancing weight gain should be given patentable weight because it is present throughout the body of the claim.

The Examiner cites *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) in support of his argument that the preamble should not be given patentable weight. The *Hirao* patent application involved a product-by-process claim. The Board found that "the preamble merely recites the purpose of the process; the remainder of the claim (the three process steps) does not depend on the preamble for completeness, and the process steps are able to stand alone." The claims of the present invention are not product-by-process claims, but are instead method claims. The preamble here does not merely recite the purpose of the method, but instead breathes life into the method. The application claims "a method for enhancing weight gain." Without this limitation, the claim could not stand on its own.

The Examiner also cites *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951) in support of his argument. The *Kropa* Court, however, found that the preamble was essential to point out the invention defined by the claim. The Court

stated that “where the preamble to the claim or count was expressly or by necessary implication given the effect of a limitation, the introductory phrase was deemed essential to point out the invention defined by the claim or count.” This is the case for the claims of the present invention. The recitation of enhancing weight gain defines the invention defined by the claims. It is only by that phrase that it can be known that the subject matter of the claims is a method for enhancing weight gain.

Because the recitation of enhancing weight gain is not limited to the preamble of the claim, but rather, is present throughout the body of the claim, the phrase must be given patentable weight. Further, even if the phrase were limited to the preamble, it should still be given patentable weight based on its necessity in defining the invention.

The Examiner lastly asserts that “appellants fail to establish unexpected result sufficient to rebut the prima facie obviousness.” The Examiner incorrectly asserts that the references “teach that DHA and ARA are necessary for preterm infant to proper growth and development.” As stated above and previously in Applicant’s Appeal Brief, the references do not teach that DHA and ARA are necessary for the proper growth of preterm infants. The cited references illustrate that at the time of the invention, persons of ordinary skill believed that DHA supplementation would depress weight gain in preterm infants. The present invention demonstrates that not only does DHA and ARA supplementation negate DHA’s weight depressing effect, but it also enhances the weight gain of preterm infants beyond that which is shown in unsupplemented preterm infants. These results would clearly have been unexpected and surprising to one of ordinary skill in the art at the time of the invention. As such, that which would have been surprising to a person of ordinary skill in the art could not have been obvious.

In summary, the present invention discloses a method for enhancing the weight gain of preterm infants through the administration of DHA and ARA to those infants. None of Kyle, Crozier, or Schwikhhardt suggest the use of DHA and ARA for this purpose. Thus, it is respectfully requested that Applicant's Appeal be granted and a patent issue based on the above-captioned application.

Please charge any additional fees required by this Appeal Brief to Deposit Account No. 50-2548.

Respectfully requested,

NELSON MULLINS RILEY & SCARBOROUGH

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